Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN D. KALVELAGE, IAN E. SALDITCH, GALEN NICKEY, JR. and TOOMAS OTS

Appeal No. 2004-0220
Application No. 09/734,196

HEARD: February 17, 2004

Before ABRAMS, FRANKFORT, and STAAB, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

REMAND TO THE EXAMINER

The above identified application is being remanded to the examiner under the authority of 37 CFR § 1.196(a) and MPEP § 1211 for appropriate action with regard to the items listed below.

BACKGROUND

Independent claims 1 and 13 on appeal were amended in a paper filed April 25, 2002 (Paper No. 4) to respectively define a

sealed blister assembly wherein a plastic sheet having a recess formed therein and a plastic lid adapted to attach to the perimeter of the recess are specifically configured to cooperate with one another to form an "impermeable seal" and thereby define a sealed blister (claim 1), and a package assembly for dispensing a pharmaceutical medication comprising a plastic sheet having a medication receiving recess therein, a pharmaceutical medication positioned in the recess, and a plastic lid positioned in overlying relationship to the plastic sheet and recess, and configured with a raised ridge having an outside edge corresponding to the perimeter of the recess and frictionally engaging the perimeter to thereby close the recess and "impermeably seal" the medication therein (claim 13). On page 2 of the specification, appellants note that an objective of the invention is to provide a sealed blister assembly that does not require an adhesive or heat sealing process to seal a blister sheet and lidding sheet in order to form an "impermeable seal." It is appellants' intention that such a seal be formed "solely by engagement of an undercut in the plastic sheet and a shoulder in the plastic lid" (specification, page 1).

In the brief (Paper No. 15, page 4) appellants note that a preferred embodiment of the invention is as a medication package, and emphasize that there are strict and special requirements for such packaging, and that such packaging cannot be used and sold if it performs at less than rigorous impermeability standards. In the paragraph bridging pages 1 and 2 of the reply brief (Paper No. 18) appellants urge that "an essential element" of their invention is the "impermeable" nature of the seal of the blister assembly and contend that it was for that reason the "impermeable" limitation was added to independent claims 1 and 13.

Principal arguments in both the brief and reply brief urge that the seals present in Allers et al. (U.S. Patent No. 5,860,549) and Edwards et al. (U.S. Patent No. 5,339,973), applied by the examiner under 35 U.S.C. § 102(b) against independent claims 1 and 13, are not "impermeable seals" and that those patents do not actually teach or enable a seal that could be characterized in any way as an "impermeable seal."

By definition, an "impermeable seal" is one that is "not permeable" and thus does not permit fluids such as liquids and

gases to pass through it.[1] Therefore, the term "impermeable seal" used in appellants' independent claims 1 and 13 on appeal would appear to mandate a seal that is impervious to gases and liquids and is incapable of being passed through or penetrated by such fluids. However, notwithstanding the use of the terminology "impermeable seal" in the above-noted portions of appellants' specification and the argued fact that the impermeable nature of the seal is an "essential element" of appellants' invention, we note that appellants' own specification (pages 7 and 8) provides evidence that the seal formed in the present invention is not impervious to gases and liquids and thus incapable of being passed through or penetrated by such fluids. Accordingly, appellants' own specification would appear to indicate that the seal of the present invention is not "impermeable," but instead apparently provides an average moisture permeability rate of less than 5 mg/day, e.g., on the order of 3.2-3.5 mg/day. While this is apparently a low permeability rate, it nonetheless makes clear that appellants' seal is not "impermeable." Thus, we are at somewhat of a loss as to exactly how we should understand the

[1] Webster's New World Dictionary, second College Edition, Prentice Hall Press, 1986.

requirement in independent claims 1 and 13 on appeal which expressly set forth formation of an "impermeable seal."

ITEMS FOR CONSIDERATION ON REMAND

1. Before searching for and applying prior art to the claims of an application, it is an essential prerequisite that the claimed subject matter be fully understood. In the present case, it is abundantly clear that the examiner and appellants have not come to grips with or specifically set forth on the record exactly what the terminology "impermeable seal," added to the claims in the amendment filed April 25, 2002, is intended to mean in the context of the claims now before us on appeal. In fact, the examiner's explanation of the § 102(b) rejections of independent claims 1 and 13 found on pages 3 and 4 of the answer, does not even mention this limitation. Absent some reasoned interpretation of this claim terminology on the record, we are unable to evaluate the prior art rejections posited by the examiner. Accordingly, we remand for consideration of this issue and of whether or not appellants even have § 112, first paragraph, support for claims directed to an "impermeable seal."

2. In the § 102(b) rejections of independent claim 13, the examiner has made no effort whatsoever to address the specific combination of a package assembly and a pharmaceutical medication "positioned in" the recess of the package and impermeably sealed therein. The examiner's assertion that the food dish of Allers and the food storage container of Edwards are "fully capable of receiving medication" and that such is "merely a matter of intended use," does not explain how the specific combination recited in claim 13 is anticipated by the containers of Allers and Edwards. Accordingly, we remand for the examiner to provide such an explanation.

3. We also note the examiner's rejection of dependent claims 6-8 under 35 U.S.C. § 102(b) based on Allers, however, as urged by appellants in their brief, this patent has no specific disclosure or teaching of using "polyethylene" to form the sheet or lid of the food container therein, as is required in claims 6-8 on appeal. While the disclosure in Allers (col. 1, lines 14-15) indicates that the container therein may be formed of "a clear plastic of known type," we fail to see how this broad disclosure of a clear plastic would anticipate claims 6-8 on appeal. As for the examiner's reference on page 9 of the answer

to other patents of record which purportedly evidence that polyethylene is a conventional plastic material, we note that the rejection is under 35 U.S.C. § 102(b), not 35 U.S.C. § 103. On remand, the examiner may wish to reconsider the anticipation rejection.

4. Dependent claims 11 and 12 on appeal each set forth a limitation that the sealed blister of claim 1 is used for packaging a medication. Claim 11 then sets forth that the sealed blister "meets or exceeds the requirements to be a U.S.P. Class A individual unit-dose container," while claim 12 sets forth that the sealed blister "meets or exceeds the requirements to be a U.S.P. Class B individual unit-dose container." Our first problem with claims 11 and 12 is that there is nothing in the record to indicate exactly what the "requirements" to be a U.S.P. Class A or Class B individual unit-dose container are and how they would differ from one another. As for the examiner's rejection of these claims under 35 U.S.C. § 102(b) based on either Allers or Edwards, and the rejection thereof under 35 U.S.C. § 103(a) based on Allers alone, we find nothing in either of the applied patents that addresses U.S.P. Class A or Class B individual unit-dose containers and find the examiner's

attempt on pages 3 and 4 of the answer to treat such limitations to be wholly unavailing, since the examiner appears to merely read those limitations out of the claims. On remand, the examiner should provide an explanation of exactly what these limitations mean in the context of claims 11 and 12 on appeal, or direct appellant to do so, and then treat all of the limitations in the claims if a rejection thereof is appropriate.

5. In the rejection of claims 1, 3 through 14, 16 and 17 under 35 U.S.C. § 102(b) based on Edwards found on pages 4 and 5 of the answer, the examiner has repeatedly referenced elements of "Allers et al" in explaining this rejection, instead of pointing to elements or teachings in the Edwards patent to support the rejection. Thus, we remand for clarification of this rejection, and for the examiner to point to appropriate portions of the Edwards patent which are thought to be anticipatory of the claimed subject matter.

This application, by virtue of its "special" status, requires immediate action, see MPEP § 708.01 (item D), Eighth Edition, Aug. 2001. It is important that the Board of Patent

Appeals and Interferences be promptly informed of any action affecting the appeal in this case.

REMAND TO THE EXAMINER

NEAL E. ABRAMS
Administrative Patent Judge

CHARLES E. FRANKFORT
Administrative Patent Judge

LAWRENCE J. STAAB
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

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